# Biotech Daily

Wednesday February 26, 2025

*Daily news on ASX-listed biotechnology companies*

*** ASX, BIOTECH DOWN: GENETIC SIGS UP 14%; MEDICAL DEVEL DOWN 11%**

*** MAYNE H1 REVENUE UP 13% TO $213m, LOSS DOWN 64% TO $25.5m**

*** VITURA H1 REVENUE UP 5% TO $63m, PROFIT DOWN 48% TO $2m**

*** NOVA EYE H1 REVENUE UP 27.5% TO $13m, LOSS DOWN 4% TO $5m**

*** GENETIC SIGS H1 REVENUE UP 136% TO $8.5m, LOSS UP 45% TO $15m**

*** MICROBA H1 REVENUE UP 147% TO $8m, LOSS DOWN 50% TO $6m**

*** IMPEDIMED H1 REVENUE UP 26% TO $6m, LOSS UP 15% TO $11m**

*** CONTROL BIONICS H1 REVENUE DOWN 2% TO $3m, LOSS UP 47% TO $3m**

*** STARPHARMA H1 REVENUE DOWN 70% TO $2m, LOSS UP 5-FOLD TO $5m**

*** AROVELLA TO RAISE $15m; WITHDRAWS $20m RAISE**

*** TELIX: FDA ACCEPTS TLX250-CDx KIDNEY CANCER APPLICATION**

*** CHINA ALLOWS IMUGENE ONCARLYTICS PATENT**

*** JAPAN ALLOWS RECCE ANTI-INFECTIVES PATENT**

*** OPTHEA VALIDATES OPT-302 MANUFACTURING**

*** INVION EXPANDS HANLIM INV043 TRIAL TO OESOPHAGEAL CANCER**

*** TIFFANY OLSON REPLACES TELIX CHAIR KEVIN MCCANN; MARIE MCDONALD**

*** PROF IAN MEREDITH REPLACES MTP DIRECTOR DR NICK CERNEAZ**

## MARKET REPORT

The Australian stock market fell 0.14 percent on Wednesday February 26, 2025, with the ASX200 down 11.2 points to 8,240.7 points. Eleven of the Biotech Daily Top 40 stocks were up, 23 fell, five traded unchanged and one was untraded. The Big Caps were mixed.

Genetic Signatures was the best, up seven cents or 14.0 percent to 57 cents, with 289,116 shares traded. Atomo was up 11.1 percent; Percheron improved 8.3 percent; Amplia and Prescient were up more than six percent; Clinuvel climbed 4.1 percent; Resonance was up 3.6 percent; Orthocell, Resmed and Syntara rose more than two percent; Avita and Nanosonics were up more than one percent; with CSL up 0.9 percent.

Medical Developments led the falls, down eight cents or 10.6 percent to 67.5 cents, with 228,911 shares traded. Actinogen and Paradigm lost five percent or more; Cyclopharm, Emvision, Impedimed, Nova Eye, Opthea, Proteomics and Starpharma fell four percent or more; Polynovo and Pro Medicus were down more than three percent; Alcidion, Mesoblast, Neuren and SDI shed more than two percent; 4D Medical, Aroa, Clarity, Dimerix, EBR, Immutep and Micro-X were down more than one percent; with Cochlear and Telix down by less than one percent.

## MAYNE PHARMA GROUP

Mayne Pharma says revenue for the six months to December 31, 2024 was up 13.4 percent to $213,054,000, with net loss after tax down 63.8 percent to $25,545,000.
Mayne Pharma said revenue from sales of its women's health products was up 30.25 percent to $94.3 million, with $81.4 million from its dermatology business and $37.4 million from the manufacture and sale of its branded and generic pharmaceuticals.
The company said administration costs fell 12.0 percent to $63.9 million, with research, development, medical and regulatory expenditure down 3.5 percent to $9,886,000 and the previous foreign exchange loss of $3,538,000 turned to a $9,302,000 gain.
Mayne Pharma said diluted loss per share was down 63.2 percent to 32.3 cents, with negative net tangible assets per share up 259.6 percent to negative $1.69.
The company said it had cash and cash equivalents of $53,710,000 at December 31, 2024 compared to 109,227,000 at December 31, 2023.
Mayne Pharma was up one cent or 0.1 percent to $7.23 with 786,559 shares traded.

## VITURA HEALTH (FORMERLY CRONOS AUSTRALIA)

Vitura says that revenue for the six months to December 31, 2024 was up 4.5 percent to $62,672,501 with net profit after tax down 47.9 percent to $1,702,620.
Vitura said $50,025,196 in revenue was from sales of its medicinal marijuana products, with $12,647,305 from medical consultations and services fees including its Doctors on Demand business and the online portal Canview.
The company said the reduced profit was "largely due to a decline in the average selling price of the products sold through Canview and gross margin pressures … industry-wide".
Vitura said it incurred a "once off expense during the period relating to the decision to purchase a copy of the Canview platform as opposed to building a new platform".
Last year, the company said it would pay Code4 Cannabis $2.5 million and 5,787,037 shares, worth about $500,000, for a copy of the Canview platform and would withdraw all legal proceedings (BD: Oct 17, 2024).
Today, Vitura said diluted earnings per share fell 50.0 percent to 0.29 cents, with net tangible assets per share up 3.6 percent to 1.45 cents.
The company said that it had cash and cash equivalents of $7,396,996 at December 31, 2024 compared to $12,995,887 at December 31, 2023.
Vitura fell 1.1 cents or 11.2 percent to 8.7 cents with 1.6 million shares traded.

## NOVA EYE MEDICAL

Nova Eye says revenue for the six months to December 31, 2024, was up 27.5 percent to $12,925,000 with net loss after tax down 4.1 percent to $5,394,000.
Nova Eye said increased revenue was from improved glaucoma surgical device sales including Itrack due to "growth in all major markets", with US sales up 28 percent.
The company said its loss was "in line with the previous period due to a combination of sales growth and operating leverage from sales marketing and clinical expenditure offset by a decline in gross margin caused by production cost increases caused by supply chain problems during July to September 2024".
Nova Eye said diluted loss per share fell 20.3 percent to 2.35 cents, with net tangible asset backing per share unchanged at two cents.
The company said it had cash and equivalents of $2,258,000 at December 31, 2024 compared to $2,612,000 at December 31, 2023.
Nova Eye fell half a cent or 4.2 percent to 11.5 cents with 3.8 million shares traded.

## GENETIC SIGNATURES

Genetic Signatures says revenue for the six months to December 31, 2024 was up 135.8 percent to $8,499,000, with net loss after tax up 45.2 percent to $15,200,000.
Genetic Signatures said “the increased revenue was primarily a result of strong respiratory sales in Australia during the half year” of its Easyscreen respiratory pathogen detection kit, with the previous period impacted by a temporary sales reduction while Easyscreen underwent a design change.
The company said its loss included “impairment expenses of $6.8 million” from intangible assets relating to “instrument development and obsolete instruments in property, plant and equipment”.
Genetic Signatures said diluted loss per share per share fell 5.6 percent to 6.88 cents, with net tangible assets per share up 15.3 percent to 24.1 cents.
The company said it had cash and cash equivalents of $40,793,000 at December 31, 2024 compared to $18,124,000 at December 31, 2023.
Genetic Signatures was up seven cents or 14.0 percent to 57 cents.

## MICROBA LIFE SCIENCES

Microba says revenue for the six months to December 31, 2024 was up 147.0 percent to $8,084,136, with net loss after tax down 50.0 percent to $5,741,685.
Microba said increased revenue was from improved sales of Metaxplore microbiome test in Australia and “maintaining consistent revenues in the Invivo Clinical business in the UK as we transition to growth in that region.
In 2023, the company said it had completed the up-to $21.2 million acquisition of the Gloucestershire, England-based Invivo Clinical, a microbiome testing business with products including vaginal, oral and urinary testing (BD: Dec 6, 2023).
Today, Microba said its decreased loss was due to its increased scale as well as a reduced operating expenditure during the period, “primarily driven by lower spending on therapeutics research and development programs following the completion of large-scale discovery, validation and clinical de-risking initiatives”.
The company said diluted loss per share was down 58.6 percent to 1.28 cents, with net tangible assets per share down 35.9 percent to 2.70 cents.
Microba said it had cash and equivalents of $17,316,014 at December 31, 2024 compared to $27,846,261 at December 31, 2023.
Microba was up half a cent or 2.1 percent to 24.5 cents.

## IMPEDIMED

Impedimed says revenue for the six months to December 31, 2024 was up 25.6 percent to $6,008,000 with net loss after tax up 14.7 percent to $11,146,000.
Impedimed said revenue was from sales of its bio-impedance spectroscopy systems and software services including Sozo for lymphoedema, heart failure and malnutrition.
The company said the increased revenue “was primarily attributable to an increase in Sozo usage fees” which were up 26.7 percent to $5.7 million.
Impedimed said diluted loss per share was up 20.0 percent to 0.06 cents, with net tangible assets per share down 33.3 percent to two cents.
The company said it had cash and cash equivalents of $17,693,000 at December 31, 2024 compared to $36,905,000 at December 31, 2023.
Impedimed fell 0.2 cents or 4.4 percent to 4.3 cents with 2.4 million shares traded.

## CONTROL BIONICS

Control Bionics says revenue for the six months to December 31, 2024 was down 2.3 percent to $2,896,291 with net loss after tax up 47.1 percent to $3,222,197.
Control Bionics said revenue from sales of its Neuronode sensors and Neurostrip wearable miniaturized electro-myography fell 90.2 percent to $2,763,860, technical trials and support revenue was down 54.8 percent to $13,888,000 and lease of goods revenue fell 2.9 percent to $118,543.
The company said research and development expenditure was up 231.4 percent to $565,956, employee benefits increased 11.2 percent to $3,044,157, marketing costs rose 32.1 percent to $226,321 and raw materials and consumables expenses were up 33.8 percent to $1,063,251.
Control Bionics said diluted loss per share down 48.2 percent to 1.39 cents, with net tangible assets down 64.2 percent to 0.87 cents.
The company said that it had cash and cash equivalents of $972,229 at December 31, 2024 compared to $1,314,163 at December 31, 2023.
Control Bionics fell 0.4 cents or 9.3 percent to 3.9 cents.

## STARPHARMA HOLDINGS

Starpharma says revenue for the six months to December 31, 2024 was down 69.8 percent to $2,427,000, with net loss after tax up 5.2-fold to $5,392,000.
Last year, Starpharma said revenue for the six months to December 31, 2023 was $7,197,000 due to a one-off payment from Singapore's Mundipharma of $6.54 million after terminating its Vivagel bacterial vaginosis (BV) agreement (BD: Aug 14, 2023).
Today, the company said $1,888,000 of revenue was from sales and royalties of Viraleze and Vivagel BV and research income from Petalion Therapeutics with $539,000 from interest income.
Starpharma said diluted loss per share was up 420 percent to 1.30 cents and net tangible asset backing per share fell 25.0 percent to six cents.
The company said it had cash and cash equivalents of $20,277,000 at December 31, 2024 compared to $32,131,000 at December 31, 2023.
Starpharma fell half a cent or 4.35 percent to 11 cents.

## AROVELLA THERAPEUTICS

Arovella says it has "firm commitments" to raise about $15 million at 12.5 cents a share in replacement of a $20 million placement earlier this year.
Last month, Arovella said that it had raised $20 million at 17 cents a share, a 2.9 percent discount to its last closing price, in a placement (BD: Jan 19, 2025).
Today, the company today's capital raising was in place of the January placement, which had been withdrawn following the default by an Australian-based private investor to settle on its $15 million binding subscription obligation".
Arovella said investors under the $15 million placement would receive one option for every three shares issued, exercisable at 15 cents each until May 24, 2027.
The company said the funds raised would be used to complete its phase I, firs-in-human trial of ALA-101 for non-Hodgkin's lymphoma and leukemia, as well as strengthening its pipeline and general working capital purposes.
Arovella fell six cents or 30.8 percent to 13.5 cents with 14.9 million shares traded.

## TELIX PHARMACEUTICALS

Telix says the US Food and Drug Administration has accepted its biologics licence application for TLX250-CDx for imaging kidney cancer and granted it a priority review.
In 2023, Telix said it had filed an FDA biologics licence application for its positron emission tomography (PET) imaging agent TLX250-CDx for clear cell renal cell carcinoma imaging, following a 300-patient phase III trial showing TLX250-CDx had 86 percent sensitivity and 87 percent specificity (BD: Nov 7, 2022; Dec 19, 2023).
Today, the company said it had been granted priority review with a Prescription Drug User Fee Act (PDUFA) date of August 2025, paving the way for a US launch in 2025.
Telix said that, if approved, TLX250-CDx, or Zircaix, would become “the first commercially available imaging agent to accurately and non-invasively diagnose and characterize clear cell renal cell carcinoma”.
Telix precision medicine chief executive officer Kevin Richardson said the company was “delighted that the FDA has accepted this [biologics licence application] as it moves us one step closer to bringing our breakthrough product to patients”.
“We are aiming to revolutionize the management of kidney cancer, just as [prostate specific membrane antigen imaging]-PET-[computed tomography] scanning has changed the management of prostate cancer,” Mr Richardson said.
“By providing a more definitive clinical diagnosis for renal masses, we believe that Zircaix will help physicians make more timely and confident patient management decisions and more quickly provide patients with a clear understanding of their disease and treatment options,” Mr Richardson said.
“Building further on Telix’s successful urology franchise, we are preparing to bring this powerful precision medicine product to market in 2025,” Mr Richardson said.
Telix fell 14 cents or 0.45 percent to $31.00 with 1.75 million shares traded.

## IMUGENE

Imugene says the China Patent Office has allowed a patent protecting its CD19-expressing oncolytic virus Oncarlytics.
Imugene said the patent, titled ‘Oncolytic Virus Expressing a CAR-T Cell Target and Uses Thereof’ would protect intellectual property in China until 2038.
The company said Oncarlytics entered solid tumor cells and forced them to express the CD19-protein on the cell surface, presenting a target for CD19-targeting therapies.
Imugene said it was conducting an up-to 40 patient, dose-escalation trial of Oncarlytics at up-to 10 sites in the US.
Imugene was unchanged at 3.6 cents with 35.1 million shares traded.

## RECCE PHARMACEUTICALS

Recce says the Japan patent Office has allowed Patent Family Four protecting its anti-infectives, including R327 and R529.
Recce said the patent, titled ‘Process for Preparation of Biologically Active Copolymer’ would protect its intellectual property until 2041.
The company said the patent related to process of preparation for its anti-infectives, their use as a treatment of bacterial and viral infections as well as their administration by oral, inhalation, transdermal delivery, aerosol, gel, topical foam or ointment.
Recce said it had received Family Four patents in Australia, Canada and Israel, “with further patent cooperation treaty country submissions in respective stages”.
Recce fell 1.5 cents or 3.4 percent to 43 cents.

## OPTHEA

Opthea says it has validated the manufacturing process of OPT-302 for wet age-related macular degeneration (AMD), readying it for a biologics licence application.

Last year, Opthea said that it had completed quality control manufacture of sozinibercept, or OPT-302, producing three successful, consecutive, commercial-scale drug batches (BD: Sep 19, 2024).

Today, the company said it had completed its "process performance qualification" campaign for sozinibercept, having successfully produced three consecutive commercial-scale drug product batches.

Opthea said the validation was in preparation for a potential biologics license application filing and commercialization of sozinibercept in wet age-related macular degeneration.

Opthea chief executive officer Dr Frederic Guerard said validating the manufacturing process was "a critical step in support of a potential [biologics licence application] filing of sozinibercept in wet AMD in the first half of 2026".

"As we continue to work towards the phase III topline data readout of 'Coast' in the months to May 31, 2025, and 'Shore' in mid-2025, we now have demonstrated our ability to consistently manufacture quality drug product at commercial scale to support a potential approval and launch of sozinibercept in wet AMD," Dr Guerard said.

In 2021, Opthea said it had treated the first of about 1,980 patients in the US and Canada, for its two randomized, double-blind, controlled trials evaluating the safety and efficacy of OPT-302 in combination with either ranibizumab (Shore) or aflibercept (Coast) compared to ranibizumab or aflibercept alone (BD: Mar 15, 2021).

Opthea fell 4.5 cents or 4.7 percent to 91.5 cents with 3.3 million shares traded.

## INVION

Invion says it has expanded its pre-clinical trial collaboration with Hanlim Pharma Co Ltd for INV043 to include oesophageal cancer in addition to glioblastoma.

Last year, Invion said it had a two-year partnership with Seoul, South Korea's Hanlim Pharma to conduct proof-of-concept, in-vivo studies of its Photosoft INV043 for brain cancer (BD: May 8, 2024).

Today, the company said Hanlim would fund all pre-clinical studies on oesophageal cancer and glioblastoma, with the studies taking place at South Korea's K-Medi hub, while Invion would retain all rights to its Photosoft technology and any intellectual property resulting from the collaboration.

Invion said that successful pre-clinical results "could lead to a co-development agreement".

Invion managing-director Thian Chew said the partnership was "an opportunity to demonstrate the potential of Photosoft on oesophageal cancer, which has a poor survival rate, while working with the expertise and resources of the international pharmaceutical group, Hanlim".

"The partnership with Hanlim complements Invion's other development efforts, including our current phase I/II non-melanoma skin cancer trial and proposed phase I/II anogenital cancer trial," Mr Chew said.

"Demonstrating that Photosoft is both safe and effective in selected cancer indications with unmet needs will provide new therapeutic options to doctors and patients," Mr Chew said.

Invion was up half a cent or 3.6 percent to 14.5 cents.

## TELIX PHARMACEUTICALS

Telix says director Tiffany Olson will replace Kevin McCann as chair and Marie McDonald has been appointed as a non-executive director.

Telix said Mr McCann would retire on May 21, 2025, had been chair since its ASX-listing in November 2017 and his “tireless service and strategic direction have been instrumental to Telix’s growth and success”.

The company said the Indianapolis, Indiana-based Ms Olson’s appointment would be effective following Mr McCann’s retirement and said she had been appointed non-executive director in March 2022 and had experience in commercialization and corporate strategy in oncology, including radio-pharmaceuticals (BD: Mar 31, 2022).

Telix said the Melbourne-based Ms McDonald’s appointment was effective March 3, 2025, and that she had been director of ASX-listed companies CSL and Nanosonics.

Telix managing-director Dr Christian Behrenbruch said the company was “immensely thankful for Mr McCann’s outstanding service to Telix as our inaugural chairman”.

“He has consistently stood for a high standard of corporate governance, a patient-centric company culture and a strong focus on shareholder value creation,” Dr Behrenbruch said.

“Mr McCann has also been a personal mentor and supporter during a period of extremely rapid growth, for which I am personally grateful,” Dr Behrenbruch said.

“I am very welcoming of Ms Olson and Ms McDonald’s leadership and what it means for the future trajectory of Telix” Dr Behrenbruch said.

## MTP CONNECT

MTP Connect says it has appointed Prof Ian Meredith as a non-executive director after the retirement of inaugural, nine-year non-executive director Dr Nick Cerneaz.

MTP Connect said Prof Meredith had been chief medical officer at Boston Scientific as well as a clinical and interventional cardiologist at Melbourne’s Monash Health.

According to his Linkedin profile, Prof Meredith was a director of Breakthrough Victoria and the Bio-Melbourne Network and held a Bachelor of Science, Bachelor of Medicine, Bachelor of Surgery and Doctor of Philosophy from Melbourne’s Monash University.

MTP Connect chair Jaala Pulford said Prof Meredith had “a wealth of clinical and industry experience and a unique global perspective to the MTP Connect board and our work to unlock the potential of Australia’s medical product innovators”.

“Along with my colleagues on the board, I also want to acknowledge and thank Dr Cerneaz for his invaluable contribution over the last nine years to MTP Connect and the broader life sciences sector,” Mr Pulford said.

“Dr Cerneaz has been engaged from the very beginning with the critical evolution of MTP Connect from an impactful industry growth centre into Australia’s life science innovation accelerator, and we thank him for his unwavering support of our mission in supporting development of home-grown medical innovations,” Mr Pulford said.